

REMARKS

Status of the Claims

Claims 1, 3-10, 12-16, and 27-34 were pending in the present application. Applicants have amended claims 1, 12, and 27. Applicants have added new claim 35. Applicants submit that these amendments add no new matter. After entry of this amendment, claims 1, 3-10, 12-16, and 27-35 will be pending in this application.

Support for Claim Amendments

Claim 1 has been amended to recite a sample holder system for holding a plurality of samples for use in an automated sample analyzer. The system comprises a first well strip comprising a plurality of wells arranged in a linear array. Support for these amendments is found throughout Applicants' specification as filed, for example, at least at page 1, paragraph 2.

Claims 1, 12, and 27 have been amended to delete the word "inseparably." Claims 1, 12, and 27 have also been amended to insert the phrase "arranged in a linear array." Support for these amendments are found throughout Applicants' specification as filed, for example, at least at page 1, paragraph 2.

Support for new claim 35 is found throughout Applicants' specification as filed, for example, at least at page 1, paragraph 2; at page 2, paragraphs 7-8; at pages 5-7, paragraph 31; at page 8, paragraph 37; at pages 8-9, paragraph 40; at page 10, paragraph 46; in originally filed claim 27; and in FIGS. 1, 2, 3C, and 4.

Rejections under 35 U.S.C. 112

Claims 1, 3-10, 12-16, and 27-34 are rejected under 35 U.S.C. 112 as allegedly failing to comply with the written description requirement. The Office action states that "the original disclosure does not support the instant claim language of 'inseparably connected.'" Applicants respectfully disagree given that "drawings alone may provide a 'written description of an invention' as required by § 112." *Vas-Cath Inc. v. Mahurkar* 935 F.2d 1555, 1564, 19 USPQ 2d 1111, 1119 (Fed. Cir. 1991). The fact that the wells are inseparably connected is strikingly evident from at least Figures 2 and 7. For example, the side view of the well strip in FIG. 2 shows no breaks in the side of wall of the well strip. Rather, FIG. 2 shows that the side wall is

continuous from one end wall to the other. Further, the hatched cross-section in FIG. 7 shows that the wells in the well strip are formed from one continuous material without any breaks.

Without acquiescing to the rejection and solely to advance prosecution, Applicants have amended claims 1, 12, and 27 to remove the word “inseparably.” Therefore, Applicants respectfully request that the rejection of claims 1, 3-10, 12-16, and 27-34 be reconsidered and withdrawn.

Rejections under 35 U.S.C. 102(b)

Claims 1-2, 3-10, 12-16, and 27-34 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent No. 5,285,907 to Franchere *et al.* (“Franchere”). Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Claim 2 was canceled in the Amendment and Response to Restriction Requirement filed on July 1, 2004. Therefore, Applicants respectfully request that the Examiner withdraw the rejection with respect to claim 2.

It is well settled law that an anticipating reference must teach each and every element of a claimed invention. *Glaxo, Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995). Applicants submit that Franchere does not teach each and every element of the claimed invention. Therefore, for the reasons outlined below, Franchere is an improper reference under 35 U.S.C. 102(b).

Independent claims 1, 12 and 27 each recite a well strip comprising a plurality of wells wherein each well is physically connected to an adjacent well, each of said plurality of wells for containing a fluid sample therein.

In contrast to Applicants’ claimed invention, Applicants submit that Franchere teaches modular units with a plurality of openings, each opening serving as a guide for supporting a plurality of unconnected tubes. Each tube is supported independent of another tube. The tubes, according to Franchere, may hold fluid samples. (See *e.g.* Col. 1, lines 7-15; Col. 1, lines 26-30; Col. 1, lines 47-52; Col. 3, lines 27-30; Col. 4, lines 21-28).

Franchere’s modular units, absent the insertion of and presence of a tube obtained from a source other than the modular unit, cannot contain a fluid sample as required by Applicants claimed invention. Franchere teaches that “each of the side wall panels [of the modular units]

have openings” to reduce the quantity of material required for making the modular units, to reduce the weight of the unit, and to allow for “observation of a specimen in the container supported in the modular unit.” (Col. 3, lines 1-6). Applicants submit that a modular unit with holes in the side walls is not a well for containing fluid sample for analysis as required by Applicants’ claimed invention because the sample would spill through the openings in the side wall of Franchere’s modular unit.

Further, for the sake of argument, even if Franchere’s tubes were wells, Franchere does not teach or suggest a tube or tubes physically connected to an adjacent tube or tubes for holding fluid samples. For example, neither FIG. 1 of Franchere, which shows a modular unit before it is assembled, nor FIG. 2, which shows a modular unit after it is assembled, show physically connected test tubes or containers. Not one of the modular units depicted by Franchere nor the corresponding text disclose test tubes physically connected to an adjacent test tube for holding a fluid sample. Franchere’s modular units only have openings in the top surface such that each opening supports an individual tube placed therein after assembly of the modular unit (col. 3, lines 27-30; col. 4, lines 21-28).

The Office action further states that “permanent connection (e.g., integral construction) [of the wells] would have been obvious.” Applicants submit, however, that in contrast to the claimed invention, Franchere actually teaches away from making any physical connection between Franchere’s test tubes and Franchere’s modular units. For example, Franchere teaches that the modular units are “made in a single flat sheet form with a thickness range which allows for packaging many such units in a carton for shipping” and subsequent erection by the user (col. 4, lines 29-32). Applicants’ submit that if Franchere’s test tubes were connected to Franchere’s modular units, as the Office action suggests at page 3, such single flat sheet construction and space efficient packaging, as taught by Franchere, would not be possible.

In addition, Applicants submit that Franchere teaches away from permanent connection or integral construction between Franchere’s modular units and Franchere’s test tubes on additional grounds. For example, Franchere teaches that Franchere’s modular units are used to support specimens “received by the laboratory for subsequent handling” (col. 3, lines 12-14; see also col. 1, lines 41-45; col. 4, lines 21-28). In addition, Franchere states that “it [is] important

for the laboratory technician to be able to quickly arrange for the support of large quantities of containers or tubes which arrive in the laboratory for handling" (col. 1, lines 40-44). In other words, test tubes filled with samples arrive in the laboratory and are placed in Franchere's modular units until they are taken for testing.

If the test tubes were integrally connected with Franchere's modular units, as suggested by the Office Action, they could not be removed for subsequent testing. Rather, to move a specimen from the location of the modular unit, the specimen would have to be removed from the integrally connected tube and placed in another free tube. Such additional steps would increase the risk of dropping or spilling the specimen, a problem that Franchere's invention was designed to avoid (See abstract).

Additionally, if test tubes were integrally constructed with Franchere's modular units, as the Office Action suggests, the modular units would not be able to accommodate test tubes arriving with patient samples as the modular units would already contain test tubes. Consequently, samples from the arriving test tubes would have to be transferred to the integral test tubes. This additional step would again increase the risk of dropping or spilling the specimen, a problem Franchere was attempting to avoid (See abstract).

For these reasons, Applicants submit that Franchere does not teach or suggest a well strip comprising a plurality of wells, each well physically connected to an adjacent well for containing a fluid sample therein as required by independent claims 1, 12, and 27. Consequently, Applicants submit that Franchere is an improper reference under 35 U.S.C. 102(b). Applicants therefore respectfully request reconsideration and withdrawal of the rejection of independent claim 1 and claims 3-10 and 28-31 depending from claim 1, independent claim 12 and claims 13-16 and 32-34 depending from claim 12, and independent claim 27.

Claim 35

Applicants have introduced new claim 35 which recites a sample holder system comprising a first well strip comprising a plurality of wells for containing a fluid sample therein, and a first and second side wall. Each well is physically connected to an adjacent well and each of the plurality of wells for containing the fluid sample comprises a base and said first and

second side wall. There is a first flange on the first end of the first side wall and a first flange on the second end of the second side wall.

Applicants submit that claim 35 is patentable in view of Franchere. Firstly, whereas Applicants submit that the modular unit of Franchere cannot hold a fluid due to the perforations in the side walls as discussed *supra*, Applicants claimed invention recites that the plurality of wells are for containing a fluid sample therein. Secondly, even if Franchere's test tubes are wells, which Applicants submit they are not, for the reasons discussed *supra*, Franchere's test tubes are not physically connected to an adjacent test tube.

Furthermore, claim 35 requires that the plurality of wells for containing fluid each comprise a base and the first and second side wall of the well strip. The first side wall has a flange and the second side wall has a flange. Applicants submit that Franchere does not teach a well for containing fluid wherein each well comprises a base and the first and second side wall of the well strip, the first and second side wall having flanges. Rather, only Franchere's test tubes hold fluid samples according to Franchere's teachings. However, Franchere does not teach or suggest that the walls of the test tube which contain the sample have flanges.

For these reasons, Applicants submit that claim 35 is patentable in view of Franchere.

CONCLUSION

Applicants submit this application is in condition for allowance and request favorable action. The Examiner is invited to telephone the undersigned representative at the number indicated below to discuss any outstanding issues.

Respectfully submitted,

Date: October 23, 2006
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